

## **IN THE CLAIMS:**

Claims 1 and 2 (Cancelled).

3. (Currently Amended) The composition of claim ~~4~~ 4, wherein the controlled release system is selected from the group consisting of:

microencapsulation in coatings of variable thickness, each with a different dissolution pattern;

encapsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and

binding bioadhesives that adhere to the wall of the small intestine.

4. (Currently Amended) ~~The composition of claim 1, wherein the composition further consists essentially of a therapeutically effective amount of~~ An oral composition for use in treating symptoms of benign prostatic hyperplasia, consisting essentially of:

a therapeutically effective amount of a saw palmetto extract;

a phytotherapeutic agent that minimizes smooth muscle contractions; and

a controlled release system, wherein said controlled release system consists essentially of:

a coating formed from a material impervious to acidic conditions in the stomach that is soluble in the duodenum and small intestine.

5. (Previously Presented) The composition of claim 4, wherein the phytotherapeutic agent is selected from the group consisting of Belladonna Alkaloid, Choleus Forskholi, European Goldenrod, Peppermint, and Passion Fruit seed.

Claims 6 and 7 (Cancelled).

8. (Currently Amended) The composition of claim 9 ~~6~~, wherein the controlled release system is selected from the group consisting of:

microencapsulation in coatings of variable thickness, each with a different dissolution pattern;

capsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and

binding bioadhesives that adhere to the wall of the small intestine.

9. (Currently Amended) ~~The composition of claim 6, wherein the composition further consists essentially of~~ An oral composition for improving the effectiveness of saw palmetto extract therapy, consisting essentially of:

a therapeutically effective amount of a saw palmetto extract;

a therapeutically effective amount of a phytotherapeutic agent that minimizes smooth muscle contractions; and

a controlled release system, wherein said controlled release system consists essentially of:

a coating formed from a material impervious to acidic conditions in the stomach that is soluble in the duodenum and small intestine.

10. (Previously Presented) The composition of claim 9, wherein the phytotherapeutic agent is selected from the group consisting of Belladonna Alkaloid, Choleus Forskholi, European Goldenrod, Peppermint, and Passion Fruit seed.

11. (Currently Amended) An improved oral saw palmetto extract composition, consisting ~~consists~~ essentially of:

a therapeutically effective amount of a saw palmetto extract;

a therapeutically effective amount of a phytotherapeutic agent that reduces smooth muscle contractions; and

a controlled release system, wherein said system is selected from the group consisting of:

microencapsulation in coatings of variable thickness, each with a different dissolution pattern;

encapsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and

binding with bioadhesives that adhere to the wall of the small intestine.

12. (Currently Amended) A method of treating benign prostatic hyperplasia, comprising the step of:

administering a therapeutically effective amount of a saw palmetto extract in combination with a therapeutically effective amount of a phytotherapeutic agent that reduces smooth muscle contractions ~~which comprises further comprising~~ an oral delivery vehicle comprising a coating formed from a material impervious to acidic conditions in the stomach ~~that~~ which is soluble in the duodenum and small intestine.

13. (Original) The method of claim 12, wherein the saw palmetto extract is released into the bloodstream over an extended period.

14. (Currently Amended) The composition of claim 12, wherein the ~~controlled release system~~ oral delivery vehicle is selected from the group consisting of:

microencapsulation in coatings of variable thickness, each with a different dissolution pattern;

encapsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and

binding bioadhesives that adhere to the wall of the small intestine.

15. (Original) The method of claim 12, wherein the coating passes through the stomach intact.

16. (Original) The method of claim 12, wherein the saw palmetto extract is initially released in the duodenum.

17. (Original) The method of claim 12, wherein the saw palmetto extract is released before it enters the colon.

18. (Currently Amended) A method of improving the efficacy of saw palmetto extract treatment, comprising the steps of:

providing a therapeutically effective amount of a saw palmetto extract ~~in an oral formulation~~;

providing a therapeutically effective amount of a phytotherapeutic agent that reduces smooth muscle contractions; and

encapsulating the saw palmetto extract and the phytotherapeutic agent in a coating formed from a material impervious to acidic conditions in the stomach ~~that~~ which is soluble in the duodenum and small intestine.

19. (Original) The method of claim 18, wherein the saw palmetto extract is released into the bloodstream over an extended period.

20. (Currently Amended) The composition of claim 18, wherein the ~~controlled release system~~ coating is selected from the group consisting of:

microencapsulation in coatings of variable thickness, each with a different dissolution pattern;

encapsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and

binding bioadhesives that adhere to the wall of the small intestine.

21. (Original) The method of claim 18, wherein the coating passes through the stomach intact.

22. (Original) The method of claim 18, wherein the saw palmetto extract is initially released in the duodenum.

23. (Original) The method of claim 18, wherein the saw palmetto extract is released before it enters the colon.

Claims 24-27 (Cancelled).